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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,654	02/03/2004	Uwe Heinelt	DEAV2003/0007 US NP	1658

5487 7590 06/11/2007

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EXAMINER	
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ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
06/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/770,654	HEINELT ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) *4-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

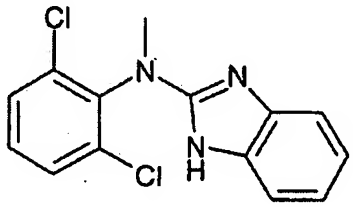
Claims 1 and 3-13 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-3, 12 and 13), and the species of Example 2 found on page 16 of the instant specification (reproduced below), in the reply filed on January 5, 2007 was acknowledged in the previous Office Action.

Example 2

(1H-Benzoimidazol-2-yl)(2,6-dichlorophenyl)methylamine hydrochloride



The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Claims 4-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 5, 2007.

Terminal Disclaimer

The terminal disclaimer filed on March 28, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent matured from 10/771,185 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Objections

Claim 1 is objected to because of the following informalities: in claim 1, under the definition of R6 and R7, "C_1-C_3-alkyl", second occurrence, is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, since R6 and R7 do not represent hydrogen per the current amendment to independent claim 1, the proviso at the end of claim 1 which states "provided that R6 and R7 are not hydrogen" makes claim 1 confusing and therefore, indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishi et al. (JP 02-306916) and Hofmeister et al. {WO 2002/46169}, each taken alone or in combination with each other. Since the WO is in a non-English language, the U.S. equivalent, U.S. Patent 6,686,384, will be referred to hereinafter. Also find provided, an English translation of JP 02-306916.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims benzimidazole compounds. Nishi et al. {see supplied English abstracts; page 101 (or page 1), and especially Compound 23 on page 140 (or page 40) of the Japanese patent; and pages 3-5, page 12 (first full paragraph), page 51 (Embodiment 23) and pages 36-38 of the provided English translation} and Hofmeister et al. {columns 1-4 and 9-12; and especially Compound 1 in column 7, line 36} each teach benzimidazole compounds which are structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of Nishi et al. and the compounds instantly claimed is that the instant claimed compounds are generically described in Nishi et al.

The difference between the compounds of Hofmeister et al. and the compounds instantly claimed is that of a secondary amine in Hofmeister et al. versus a tertiary amine as instantly claimed {i.e., -NH- in Hofmeister et al. verus -NR5- wherein R5 is alkyl as instantly claimed}.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964).

Additionally, it is sufficient if a reference compound is so closely related to claimed compound that

a chemist would find the difference an obvious variation; thus, claims are refused where the difference is primarily the one which exists between a secondary and a tertiary amine. *Ex parte Bluestone*, 135 USPQ 199 (1961).

The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating ischemic cardiopathy).

One skilled in the art would thus be motivated to prepare products embraced by Nishi et al., or alternatively, a tertiary amine compound of the secondary amine compounds taught by Hofmeister et al., to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, ischemic cardiopathy. Since each of Nishi et al. and Hofmeister et al. teach benzimidazole compounds that are structurally similar to each other and are useful

in treating some of the same diseases/disorders, the combination of Nishi et al. and Hofmeister et al. would also teach the instant claimed invention. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed May 28, 2007 have been fully considered but they are not persuasive. Applicant argues that: (1) the compounds in the prior art are not structurally similar to the instant claimed compounds; (2) Nishi et al. do not disclose any (benzoimidazol-2-yl)phenylamine compounds which are substituted in one or both of the ortho-positions of the phenyl ring as required in the currently claimed compounds; (3) Nishi et al. do not suggest the use of the claimed compounds as NHE-3 inhibitors for the

treatment or prophylaxis of a disorder of the respiratory system; (4) the claimed compounds of the present invention are not obvious in view Hofmeister et al. due to the difference in solubility; and (5) one cannot combine the teachings of Hofmeister et al. with that of Nishi et al. to arrive at the instant claimed compounds since the references teach away from the instant claimed compounds.

All of Applicant's arguments have been considered but have not been found persuasive. Applicant claims benzimidazole compounds. Nishi et al. and Hofmeister et al. each teach benzimidazole compounds which are structurally similar to the instant claimed compounds and each other. It would appear that Applicant is arguing that if a rejection under 35 USC § 102 can not be made, than a rejection under 35 USC § 103 should not be made. However, this is not one of the factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for

establishing a background for determining obviousness under 35 U.S.C. 103(a).

Further, contrary to Applicant's argument, Nishi et al. do teach (benzoimidazol-2-yl)phenylamine compounds which are substituted in one or both of the ortho-positions of the phenyl ring as required in the currently claimed compounds. See, for example, the definition of optionally substituted phenyl in Nishi et al. on page 12, first full paragraph, of the provided English translation. Specifically note "2,6-dichlorophenyl".

Applicant argues that Nishi et al. do not suggest the use of the claimed compounds as NHE-3 inhibitors for the treatment or prophylaxis of a disorder of the respiratory system. In response, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 16

U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990). Applicant argues that the claimed compounds of the present invention are not obvious in view Hofmeister et al. due to the difference in solubility. In response, the instant specification does not disclose that solubility is an important factor in the instant claimed invention or that improved solubility is Applicant's invention.

Applicant argues that one cannot combine the teachings of Hofmeister et al. and Nishi et al. In response, since each of Nishi et al. and Hofmeister et al. teach benzimidazole compounds that are structurally similar to each other and are useful in treating some of the same diseases/disorders, the combination of Nishi et al. and Hofmeister et al. would also teach the instant claimed invention. The rejection is deemed proper and therefore, maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 4-11 drawn to an invention nonelected with traverse in the reply filed on January 5, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

June 5, 2007